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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,601	01/18/2002	Frederic Robert	EGYP 3.0-019	3014

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EXAMINER	
DIAMOND, ALAN D	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,601	ROBERT, FREDERIC	
	Examiner	Art Unit	
	Alan Diamond	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03212002, 04152002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because Figures 1C, 2B, 3B, 4B, and 5B are not clear. It cannot be seen exactly what these figures are showing. Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

2. Applicant is advised that should claim 6 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both

cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, at line 1, the term "biological buffer" should be changed to "the biological buffer" so as to clearly point out which biological buffer is intended.

In claim 19, it appears that the term "C_6 to C_1" should be changed to "C_6 to C_{10}".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 10-14, 16, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Grushka et al, U.S. Patent 5,660,701.

Grushka et al analyzes drug free normal serum using free solution capillary electrophoresis in a capillary tube containing 25 mM glycine buffer (pKa of 9.8), 25 mM of NaCl (which reads on the instant additive that increases ionic strength), wherein the

buffer pH has been adjusted to 11 using NaOH (instant pH-modifier) (see col. 2, lines 20-32; and Example 1 at cols. 4-5). In Example 2 at col. 5, the pH of the buffer is 9.6, which reads on the pH of "about 10" in instant claim 23. The protein constituents that are separated by migration and detected are albumin, gamma globulin, β-globulin, α_1-globulin, and α_2-globulin (see col. 5, lines 5-9). The capillary tube is made from fused silica (see col. 4, line 55). Since Grushka et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

7. Claims 1-11, 16, 17, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Keo et al, U.S. Patent 5,599,433.

Keo et al teaches the capillary zone electrophoresis (CZE) of glycosylated proteins in clinical specimens, wherein the buffer system contains, for example, 100 mM CAPS (which reads on the instant biological buffer), 300 mM sodium borate (which reads on the instant additive that increases ionic strength), and NaOH for adjusting the pH to 11 (see col. 3, lines 32-55; col. 4, lines 43-49; col. 5, line 16 through col. 6, line 14; and col. 8, lines 32-43). The sodium borate concentration can be 50 to 200 mM (see col. 5, lines 43-65). As an alternative to the above, the sodium borate reads on the instant biological buffer, and the CAPS reads on the instant additive that increases ionic strength. Since Keo et al teaches the limitations of the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-5, 10-14, 16, 17, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grushka et al, U.S. Patent 5,660,701.

Grushka et al analyzes drug free normal serum using free solution capillary electrophoresis in a capillary tube containing 25 mM glycine buffer (pKa of 9.8), 25 mM of NaCl (which reads on the instant additive that increases ionic strength), wherein the buffer pH has been adjusted to 11 using NaOH (instant pH-modifier) (see col. 2, lines 20-32; and Example 1 at cols. 4-5). In Example 2 at col. 5, the pH of the buffer is 9.6, which reads on the pH of "about 10" in instant claim 23. The protein constituents that are separated by migration and detected are albumin, gamma globulin, β-globulin, α_1-globulin, and α_2-globulin (see col. 5, lines 5-9). The capillary tube is made from fused silica (see col. 4, line 55). Although Grushka et al exemplifies a concentration of 25 mM for the NaCl, Grushka et al is not limited to this concentration. In particular, Grushka et al teaches that the salt additive for increasing ionic strength, such as NaCl, can be present at a concentration of about 1 to about 100 mM (see col. 4, lines 9-19). Grushka et al teaches the limitations of the instant claims other than the difference which is discussed below.

Grushka et al does not require that said NaCl be present at a concentration of more than 50 to less than 200 mM, as per instant claim 17. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an NaCl concentration of, for example, 100 mM because such is clearly

within the scope of Grushka et al's disclosure. As noted above, Grushka et al teaches that the salt additive for increasing ionic strength, such as NaCl, can be present at a concentration of about 1 to about 100 mM.

10. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grushka et al as applied to claims 1-5, 10-14, 16, 17, and 22-25 above, and further in view of Ohmura et al, U.S. Patent 5,521,287.

Grushka et al is relied upon for the reasons recited above. Grushka et al teaches that the salt to increase the ionic strength of the buffer can be an inorganic salt, such as NaCl (see col. 4, lines 9-19). Grushka et al does not specifically teach that said inorganic salt can be sodium sulfate, as in instant claim 15. Ohmura et al teaches that salts for adjusting ionic strength include NaCl and sodium sulfate (see the paragraph bridging cols. 7 and 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the NaCl in Grushka et al's buffer with sodium sulfate because the substitution of art recognized equivalent salts for adjusting ionic strength, as shown by Ohmura et al, would have been within the skill of an artisan.

11. Claims 1-14, 16, 17, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauer et al, "Capillary Zone Electrophoresis of Proteins in Untreated Fused Silica Tubing," Anal. Chem., Vol. 58, pages 166-170 (1986), in view of Alter et al (U.S. Patent 5,753,094).

Lauer et al teaches the capillary zone electrophoresis (CZE) of proteins using CAPS buffer at a concentration of 20 mM at pH 11, wherein the buffer system further

includes 10 mM KCl (instant additive that increases ionic strength), and wherein pH is adjusted with KOH or HCl pH modifier (see pages166-168; and in particular, Figure 1 at page 168). Lauer et al teaches the limitations of the instant claims other than the differences which are discussed below.

Lauer et al separates model proteins using said CZE (see Table I), but does not specifically teach the separation of the constituents of a clinical sample. Alter et al teaches that CZE permits the analysis and rapid and efficient separation of constituents of clinical samples, such as serum proteins, i.e., albumin, globulin, etc (see col. 1, line 56 through col. 2, line 13; and col. 6, lines 37-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used Lauer et al's CZE so as to analyze and separate clinical samples containing protein because CZE permits the analysis and rapid and efficient separation of constituents of clinical samples, such as serum proteins, i.e., albumin, globulin, etc, as taught by Alter et al.

As noted above, Lauer et al teaches 10 mM KCl in Figure 1. Figure 4 uses 20 mM KCl. Lauer et al does not specifically teach a concentration of more than 50 mM and less than 200 mM, as in instant claim 17. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a higher concentration of the KCl in Lauer et al's buffer, such as more than 50 mM and less than 200 mM, so as to adjust the ionic strength of the buffer.

12. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lauer et al in view of Alter et al as applied to claims 1-14, 16, 17, and 22-25 above, and further in view of Ohmura et al (U.S. Patent 5,521,287).

Lauer et al in view of Alter et al, as relied upon for the reasons recited above, teaches the limitations of claim 15, the difference being that Lauer et al in view of Alter et al does not specifically teach the use of sodium sulfate in place of said KCl. Ohmura et al teaches that salts for adjusting ionic strength include KCl and sodium sulfate (see the paragraph bridging cols. 7 and 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the KCl in Lauer et al's buffer with sodium sulfate because the substitution of art recognized equivalent salts for adjusting ionic strength, as shown by Ohmura et al, would have been within the skill of an artisan.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 10/052,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the claim 23 of said

copending application, the buffer can be a zwitterionic biological buffer. As seen in the specification of said copending application the "zwitterionic biological buffer" encompassed buffers such as CAPS.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication 2002/0162744 has published from Serial No. 10/052,931.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753

Alan Diamond
June 14, 2004